

**REMARKS**

The claims have been amended in a number of aspects. First, claim 32 has been amended to consolidate the steps taken. The invention in claim 32 does not lie in obtaining a sample or extracting the nucleic acids, rather it lies in analyzing any nucleic acid extract for short RNA molecules and characterizing them. In view of the reduced number of active steps, numbering of paragraphs seems unnecessary. The added last “wherein” clause simply closes the symmetry of the claim preamble with the result. Further, claim 32 has been amended to clarify that the silencing is post-transcriptional gene silencing (PTGS) making claim 38 redundant. Claim 41 has been amended for clarification only. No new matter is added by these amendments to claims 32 or 41.

The remaining dependent claims have been shortened as a matter of style to change “A method in accordance with” to “The method of” just to make the claims read better (in the opinion of the undersigned, anyway).

There was an election of species, and accordingly, claims 33 and 34 were withdrawn. These claims have not been canceled since should a generic claim be allowed, the remaining species would be examined as the Examiner has kindly pointed out.

Claims 42-46 and 50-65 have been canceled as directed to non-elected inventions; claim 38 has been canceled as now redundant and claim 48 has been canceled as it appears unneeded and to simplify prosecution. No new matter has been added by these amendments and entry of the amendment is respectfully requested.

Turning, now, to the Office action itself and taking the issues raised in turn:

Priority

It is asserted that the limitations in claim 32 of “characterizing any SRMs which are present in the extract to determine identity or similarity with a target gene” is not supported in the priority documents.

First, applicants point out that the specification of the parent application 09/491,549 filed 26 January 2000 and the specification of the British application 99/25459.1 (a certified copy of which is of record), filed 27 October 1999 are identical with the specification of the present case. There were no claims appended to the British application, but the claims associated with the parent application as filed are identical to those that were originally filed with the present application. Support for the above phrase is found in the specification on pages 4-5, wherein it is stated that the method comprises “characterizing any SRMs which are present” and goes on to explain that “characterizing” includes methods that would show “sequence identity or similarity” (page 4, line 37-page 5, line 10). Support for the wording of this claim is also found in claim 8 of the parent as filed.

Support for “preparing a library of genes and identifying those genes in the library that share sequence identity or similarity with any SRMs” as required by claim 41 is supported in the specification on page 6 at lines 5-13. Virtually *in haec verba* support is found in claim 11 as filed originally in the present case and as filed in the parent application. Thus, the present claims are entitled at least to the priority of 26 January 2000 and applicants believe that they are further entitled to the priority of 27 October 1999.

As to the priority documents supporting the range formerly in claim 1 of 21-25 nucleotides, this issue is moot as the range has been replaced by 20-30 nucleotides which is clearly supported on page 4 of the specification, lines 9-14. The objection to the range set forth in claim 48 has been obviated by the cancellation of this claim, however applicants point out that SRMs of 23, 24 and 25 nucleotides are disclosed on page 4, lines 6-12.

Therefore, it is believed that the claims as presently presented are clearly entitled to the priority of 27 October 1999.

#### Specification

The locations of support in the specification for the phrases questioned has been pointed out in the discussion under “priority” above. Support for “characterizing any SRMs which are present in the extract such as to determine sequence identity or similarity with the target gene” is found on pages 4-5, and support for “preparing a library of genes from an organism and identifying those genes in the library which share sequence identity or similarity, with any SRMs” is found on page 6 at lines 5-13. The issue of ranges of 21-25 or 23-25 nucleotides, etc. is moot, but this is disclosed on page 4, lines 6-12.

#### Oath / Declaration

Applicants believe the declaration is adequate. First, as pointed out above, there is no supplemental subject matter added to this application. The specifications of the present application and the parent application are identical. Second, there is no cross-out as noted by the Office, the declarant has simply corrected the spelled out date to match the abbreviated date. No new declaration should be required.

Claim Objections

It is believed these have been dealt with by amendment to claim 32.

The Rejection Under 35 U.S.C. § 112, Paragraph 2

These rejections to claim 32 are either believed in error or corrected by amendment. Former step (iv) has been reworded to characterize “any” target gene and is clear that only SRMs that are present are characterized. What had been step (v) has been replaced as noted above with a closing phrase to match the preamble.

Similarly, it is believed that the amendment to claim 41 clarifies the relationship between claim 41 and claim 32. Accordingly, this basis for rejection may properly be withdrawn.

The Rejection Under 35 U.S.C. § 102

All examined claims except claim 41 were rejected as assertedly anticipated by Agrawal (WO 94/01550) as further evidenced by Bridge, et al. (*Nature Genetics* (2000) 34:263-264). Applicants appreciate that claim 41 is free of this rejection.

As the Office is certainly aware, in order for anticipation to be found, each and every limitation of the claim must be found explicitly or inherently in a single prior art document. The Office is correct that an additional document, even a document subsequent to the effective filing date of the claims in question, can be used to show what the “single” document inherently discloses. In this case, however, the “single” document, Agrawal, does not disclose either explicitly or inherently each and every limitation of claim 32, from which all the remaining rejected claims depend.

The first step required in claim 32 is to analyze a nucleic acid extract to determine the presence or absence of short RNA molecules that are 20-30 nucleotides in length in the extract. Applicants are unable to find any such step in Agrawal. Agrawal synthesizes modified antisense oligonucleotides which are then added to cells infected with HIV and the cells are analyzed for survival. Applicants are unable to find any step which analyses a nucleic acid extract for short RNA molecules.

Since no such analysis is done, it would not be possible for Agrawal to characterize short RNA molecules that are present in the extract. So the second step is not present either.

Since the claim limitations of claim 32 are not present in Agrawal, and all other rejected claims depend therefrom, this rejection may be withdrawn.

Claims 32, 35, 36, 38, 40 and 47-49 were rejected as assertedly anticipated by Baracchini, et al. (US 5,801,154). Again, applicants appreciate that claim 41 is recognized as free of this art.

This rejection is believed in error for reasons similar to those articulated with respect to Agrawal. The steps required in claim 32, from which all remaining rejected claims depend, are not conducted by Baracchini. Baracchini does not analyze any extracts for short RNA molecules, but rather feeds a short antisense molecule to cells to effect gene silencing. The only nucleic acid analysis conducted of an extract is for any messenger RNA which would be present in the absence of silencing. Accordingly, this basis for rejection may be withdrawn as well.

#### Double-Patenting

A terminal disclaimer with respect to the patent issued on the parent application, US 6,753,139 is enclosed.

Conclusion

Although it is academic with respect to the cited art, applicants have noted that they are entitled to the priority of the parent application as well as the original British filing with regard to claims 32 and 41. Applicants have further pointed to support in the specification for the limitations of these claims. As the claims are supported by the parent application, the declaration is proper, and no new oath or declaration should be required. The objections to the claims have been corrected by amendment and the rejections under 35 U.S.C. § 112 have been addressed by amendment as well. The rejections over the art are believed in error since the limitations of claim 32 are not present therein and all remaining rejected claims depend from claim 32. Claim 41 has not been rejected over the art.

Therefore, applicants respectfully request that claims 33-34 directed to non-elected species be rejoined and that claims 32-37, 39-41 and 47 be passed to issue.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 616292000110.

Respectfully submitted,

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